PRMC Policies and Procedures
Updated May 2019

The PRMC Policies and Procedures document was refreshed in May 2019. This document provides an executive summary reflecting operational changes but does not provide an exhaustive listing of all organizational and editorial changes.

Summary of Operational Changes

What requires PRMC review?

- The list of studies that do not require PRMC review has been updated to remove single patient studies (which do require administrative PRMC review) and to include non-human subjects research determination requests (which do not require PRMC review).
- Institutional studies with documented approval from a scientific review committee at an NCI-designated cancer center may undergo administrative PRMC review if documentation of SRC approval and of good standing with the NCI is provided.
- Projects for which accrual will not begin until after obtaining extramural review and funding will no longer get a separate review. The process for these projects is the same as the review process for other new studies.
- Significant amendments/changes in protocols, including major changes to the study design or risk/benefit ratio, require full committee review. This is not a procedural change but was not clearly stated in the previous iteration of the P&P.
- For studies being reviewed by external central or commercial IRBs after HRPO has approved a request to rely, proof of approval from external IRB may be submitted in lieu of local IRB documentation.

How are IRB exempt studies handled?

- Studies that are IRB exempt do not require annual renewal with PRMC. These projects still require initial PRMC approval.

How are reviewer conflicts of interest handled?

- Conflicts of interest are taken into consideration when making reviewer assignments; any committee reviewers listed on the study team for a submission will not be assigned as study reviewers and will be asked to leave the room during voting.
- In situations where both co-chairs are unable to sign PRMC review letters (due to overlapping conflicts of interest or logistical problems), another senior reviewer will sign the relevant PRMC letter(s).
- These additions to the P&P formalized the approach to conflicts of interest but did not change current practices.

Where are reviewer forms, submission forms, and work instructions located?

- Forms and instructions that were present as appendices to the P&P may now be found on the PRMC website: https://siteman.wustl.edu/research/clinical-research-resources/protocol-office-prmcqasmc/

How long do study teams have to respond to PRMC review letters?

- The window of time allotted for response to PRMC contingencies/deferrals has been decreased from 90 days to 60 days. Extensions are still permitted. Reminders will be sent at 30 days.

What is the continuing review process?

- Renewal with PRMC must be submitted at the time of IRB approval of the continuing review.
- For studies being reviewed by external central or commercial IRBs after HRPO has approved a request to rely, proof of approval from external IRB may be submitted in lieu of local IRB documentation.

How is study accrual monitored?

- Studies with zero accrual for more than 6 months will receive a notification of zero accrual with no response required. Previously, studies with zero accrual for more than 12 months were queried with justification requested from the PI.
- Studies meeting no more than 25% of annual target accrual at time of continuing review will be queried, following which consideration for extension of one year will be given. Previously, studies meeting no more than 25% of annual target accrual at time of continuing review were required to submit a justification from the PI for continued accrual.
- The document now clearly states that PRMC has ultimate oversight of accrual monitoring and study closure due to low accrual.

What is the PRMC closure process?

- For studies that are permanently closed to accrual with all participants off active intervention, the study should be closed with PRMC. Participants in follow-up that includes study-mandated procedures will be considered off active intervention if the main study intervention has been concluded.
- The study may need to remain open with the IRB but no further PRMC reviews are required.

Miscellaneous Additions

Language has been inserted throughout to make explicit reference to NCI guidelines and requirements (such as PRMC not duplicating IRB or QA functions, public availability of work instructions and review criteria).

Miscellaneous Deletions

Extraneous language describing non-PRMC functions has been removed.